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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,403	06/04/2001	Pramod K. Srivastava	8449-178-999	1802

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1643

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/873,403

Applicant(s)

SRIVASTAVA ET AL.

Examiner

Christopher H. Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,7-9,40 and 42-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-9,40 and 42-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/12/05.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Re: SRIVASTAVA *et al*

1. The amendment filed 12/12/2005 is acknowledged and entered into the record. Accordingly, claims 2-6,10-39, and 41 are canceled without prejudice or disclaimer.
2. Claims 1,7-9,40, and 42-50 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

4. The Information Disclosure Statement filed 12/12/2005 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Specification

5. The disclosure is objected to because of the following informalities:
 - a. The specification is objected to (on page 13, line 16, for example) for improper disclosure of amino acid sequences without a respective sequence identifier, i.e. a SEQ ID NOs:. Hence, the disclosure fails to comply with the requirements of 37 CFR 1.821 through 1.825. In the absence of a sequence identifier for each sequence, Applicant must provide a computer readable form (CRF) copy of the sequence listing, an initial or substitute paper copy of the sequence listing, as well as any amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as

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required by 37 CFR 1.821(e-f) or 1.825(b) or 1.825(d). *Note: Applicant is advised to review the disclosure for any other sequence non-compliant issues.*

b. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see pages 15 and 17 for example). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. *Note: Applicant is advised to review the disclosure for any other embedded hyperlinks.*

Appropriate correction is required.

Claim Rejections Withdrawn - 35 USC § 112, 1st paragraph

6. The rejection of claims 1,7-9,40, and 42-50 under 35 USC § 112, 1st paragraph as lacking adequate written description for the term “antigenic molecule” is withdrawn in view of the persuasive arguments set forth by the applicant in the paper filed on 12/12/2005. Specifically, the rejection is withdrawn in view of the fact that antigenic molecules are well known to those of skill in the art as evidenced by IDS # EN, EP, EQ.

NEW ARGUMENTS

Claim Rejections - 35 USC § 102

7. Claims 1,7-9,40, 42, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Bizik *et al* (Int. J. Cancer 1986; 37:81-88). Bizik *et al* teach the isolation of tumor associated α 2M from HMB-2 cells (a melanoma cell line, see page 81, right col) and further indicate that the α 2M is suspended in either PBS or water (see page 82,

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for example). The specification of the instant application teaches that when an antigenic molecule is present within a cell, α 2M can associate or form protein complexes intracellularly with the antigenic molecules (see page 33, lines 18-22, for example) and further indicate that such complexes can then be purified from cell culture medium from mammalian cells (see page 28, lines 5-12, for example). The α 2M isolated by Bizik *et al*, would in the absence of evidence to the contrary, comprise α 2M-antigenic molecule complexes, wherein the antigenic molecules are those that are over expressed in cancer cells relative to its expression in non-cancerous cells. Moreover, because the α 2M as disclosed by Bizik *et al* is purified to homogeneity, for the purposes of this rejection, there are at least 65% α 2M -antigenic molecule complexes. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the α 2M isolated by Bizik *et al* would not be complexed to antigenic molecules as instantly claimed, therefore because there does not appear to be any material difference between the claimed product and that of the prior art, the claims are anticipated. In the absence of evidence to the contrary, the burden is on the applicant to prove that the product claimed is different from that taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). In addition, because the product appears to be the same as that taught by Bizik *et al* the process of making the α 2M -complex (i.e. recombinantly) is not deemed a patentable distinction, unless the process makes a structurally different or distinct product. The patentability of a product does not depend on its method of production. If the product in

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the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Claim Rejections - 35 USC § 102

8. Claims 43-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Fields *et al* (J. Virol. Methods 1988; 22:283-294). Fields *et al* teach 5 different purification methods of the hepatitis B surface antigen (HBsAg) from plasma and further indicate that found in all of the purification techniques are "contaminants" of which include α 2M (see abstract for example). Fields *et al* further use the purified HBsAg which further comprises the contaminant of α 2M as preparation for immunization into a mouse (see page 288). It is also indicated that the preparation also comprises $\text{Al}(\text{OH})_3$ / aluminum hydroxide (see page 288). Although Fields *et al* do not specifically characterize that the HBsAg as being complexed to α 2M, the specification of the instant application teaches that α 2M is promiscuous in its ability to bind to proteins (see apge 3, lines 24-25) and given the fact that in all five methods of HBsAg purification as outlined by Fields *et al*, α 2M was present, in the absence of evidence to the contrary, the HBsAg as purified by Fields *et al* is complexed to α 2M. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that HBsAg preparation of the prior art is any different from the claimed composition. In the absence of evidence to the contrary, the burden is on the applicant to prove that the composition as claimed is materially different from that taught by the prior art and to establish patentable

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differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
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February 27, 2006


CHRISTOPHER YAEN
PATENT EXAMINER